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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,494	03/07/2002	Joseph M. Patti	P06331US02/BAS	2645

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	3

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/091,494	Patti et al
Examiner	**Art Unit**
P rtner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 7, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6, 11-17, and 23-41* is/are rejected.

7) ☒ Claim(s) *7-10 and 18-22* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence letter*

DETAILED ACTION

Claims 1-40 are pending.

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed June 13, 2002 has been considered.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Sequence Letter

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN the time period set for THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

5. Sequences should have SEQ ID Nos inserted; see page 30, lines 2, 14 and 21 of the instant specification.

Please Note: All claims are being read as product by process claims, wherein the claimed product may be produced by a different process that results in the same or equivalent product.

Claim Objections

6. Claims 5 and 39 are objected to because of the following informalities: Claims 5 and 39 recite abbreviations "Sdr" and "FnBP-A, FnBP-B, ClfB, CNA, EbpS and MHCII", respectively; abbreviations are permitted upon definition at their first appearance in the claims. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1,4-5, 38-40,11,15-16,23,26-28,29,30-40 are rejected under 35 U.S.C. 112, first paragraph (scope), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While specific proteins to which human immunoglobulins are taught, the now claimed genus of immunoglobulins to any clumping factor protein, any Sdr protein, and a second adhesion from any soucre, other than those sources already known in the art and described in the instant specification have not been described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Only specific proteins disclosed at page 20, definitions section that have been further defined to be Sdr proteins evidence original descriptive support (SdrC-H; and ClfA and ClfB which are also species of Sdr proteins). The now claimed genus of proteins from any species or strain of Staphylococci which are not the defined molecules disclosed in the specification has not been described. In light of the genus of second adhesins and Sdr proteins having not been

described, the genus of Sdr protein specific immunoglobulins have not been enabled, other than to those proteins that evidence original descriptive support in the instant specification.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3-10, 15-16, 23, 25-28, 30,33-34,37 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite the phrase "clumping factor A". What is source to which the immunoglobulins are screened, in light of the fact several pathogens are know to produce clumping factors, such as Candida albicans (Annaix et al (1990, abstract) , Porphyromonas gingivalis (see Nagata et al (1994,abstract)), Streptococcus, E.coli and Staphylococcus (WO85/05553) ? Clarification is requested.

Claims 1, 12,23 and 30 are directed to methods of obtaining immunoglobulin having a higher than normal antibody titer, and the last step of the method is results in a composition of antibodies that has a "higher than that found in intravenous immunoglobulin obtained from unselected donors". What is considered to be "higher than normal"? Is the level "higher than that found in intravenous immunoglobulin obtained from unselected donors" defined to be normal? Is the level of the unselected donors zero? Is any level greater than zero being claimed? How is the immunoglobulin that is purified a comparable product to intravenous immunoglobulin obtained

from unselected donors? What is the normal antibody titer recited in the preamble of the claim; all IVIG lots are not the same ?

Claims 3, 25, 28, and 34 recite the phrase " the A domain of the second staphylococcal adhesin". The adhesin of the independent claims from which claims 3, 25, 28 and 34 depend has not been defined as a domain containing protein adhesin, any type of adhesin is broadly recited and is defined to evidence clumping factor characteristics, or is an Sdr protein. Is the second adhesin a domain containing protein?

Claims 4-10 carry out an additional process step to screen for antibodies to a second adhesin, or a second staphylococcal adhesin, but the antibody composition has not been modified, only the process steps carried out. What is the source of the second adhesin? How are claims 4-5 further limiting of claim 1, which claims are directed to antibodies directed to ClfA and the composition and has not been so claimed as to --*further comprises* antibodies to a second staphylococcal adhesion--?

Claims 4,15,26, 33 are directed to a second staphylococcal adhesin. What is the biological structure, or function of the adhesin? What is the source of the second adhesin ?

Claims 5,16, and 27 recite the phrase "the second staphylococcal adhesin is a staphylococcal Sdr protein". As claim 1 does not identify ClfA as being an staphylococcal clumping factor, and multiple pathogens in addition to staphylococcus produce a clumping factor (see WO85/05553), it is not clear that the first adhesin of claim 1 is a Staphylococcal adhesin. How can the second adhesin be a second staphylococcal adhesin if the first adhesin of claim 1 is not

a staphylococcal adhesin? In the case of claims 16 and 27, which recite the phrase staphylococcal "Sdr" protein, what is the second adhesin to which the antibodies must be directed? How does the broad recitation of any Sdr protein define the presence of antibodies to an immunogen other than ClfA, as ClfA is also known to be a type of Sdr protein? Clarification of what second Sdr protein is, is requested.

Claim 37 is directed to a method of immunizing a patient and depends from claim 1 which is directed to a method of obtaining immunoglobulin. What is the composition of claim 1, since claim 1 is directed to a method and claim 1 recites two different compositions, selected and unselected intravenous immunoglobulin? Clarification of what is administered is requested.

Claims 38-40 define the second adhesin to be any one of a number of molecules, but claim 1 and 4, from which claims 38-40 depend do not define the source of the adhesin. What is the source of the adhesins? What pathogen will the immunoglobulin bind? Is the immunoglobulin recovered and treated after being identified?

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

12. Claims 11,22, 29 and 36, are rejected under 35 U.S.C. 102(e) as being anticipated by Foster et al (US Pat. 6,008, 341, reference of record).

Foster et al disclose immunoglobulin compositions (see col. 2, lines 51-54; col. 10, lines 63-67) directed to domain A (ClfA, see co. 6, line 15; col. 9, lines 36-37), which comprise antibodies of a titer that is 2x that of the control (see col. 8, lines 30-33) of fibronectin binding protein, a Sdr protein (domain R, see col. 6, line 17) together with other blocking components (see col. 11, lines 11-14). The immunoglobulin compositions anticipate the instantly claimed invention.

13. Claims 11-22, 29-36,41 are rejected under 35 U.S.C. 102(e) as being anticipated by Gristina et al (US Pat 5,718,899 or US Pat. 5,707,627).

The claimed invention is directed to a method of obtaining a composition of human immunoglobulin with immunoreactivity with S.aureus surface expressed adhesins, the adhesins being ClfA and Sdr proteins and immunoglobulin produced by this method.

(Instant claims 11,22,29 and 36) Gristina disclose human immunoglobulins compositions directed against Staphylococcal adhesins, obtained by the method of:

administering (immunized donors, see col. 9, line 53),

obtaining or recovering blood or plasma ("obtained", see col. 9, line 53),

selecting high titer donor blood or plasma (see col. 9, line 54),

treating the donor blood or plasma (see fractionation, col. 9, line 50) to obtain immunoglobulins in a concentrated state.

The immunoglobulins are taught to include immunoglobulins directed the S.aureus and S.epidermidis adhesin molecules (see abstract; col. 7, lines 47-50; col. 9, lines 7-15; and claims). (Instant claims 12-21, 30-35, 41) The human immunoglobulin to S.aureus and S.epidermidis was obtained by the method comprising the steps of :

administering S.aureus antigens to a human (see abstract, col. 9, lines 45-56; Table 7; col.. 12, lines 9-10, and lines 59-60);

recovering blood or plasma;

treating the blood or plasma to obtain pooled human immune globulin (see col. 4, claim 1, subparagraph (c)).

In light of WO94/13310, WO94/18327 and WO95/34655, the S.aureus and S.epidermidis strains comprised Sdr and clumping factor adhesins.

Inherently the immunoglobulin compositions of Gristian anticipates the instantly claimed invention, in light of the claims reciting "open" language permitting any number of S.aureus immunogens to be used to be administered to a human host for induction of immunoglobulin.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

14. Claims 11, 12-17, 22, 29, 30-36 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephan et al (US Pat. 4,965,068, reference of record) in light of (WO94/13310), WO94/18327 and WO95/34655.

The claimed invention is directed to a method of obtaining a composition of human immunoglobulin with immunoreactivity with S.aureus surface expressed adhesins, the adhesins being ClfA and Sdr proteins and immunoglobulin produced by this method.

(Instant claims 11,22,29 and 36) Stephan et al disclose and claim a composition of human immunoglobulin with immunoreactivity with S.aureus surface expressed immunogens (see col. 6,

claim 16 and 17), wherein the strain of S.aureus would inherently comprise bacterial pathogen expressed adhesins ClfA and Sdr protein.

(Instant claims 12-17; 30-35, 41) The human immunoglobulin to S.aureus was obtained by the method comprising the steps of :

administering S.aureus antigens to a human (see col. 4, claim 1, subparagraph (a)),

recovering blood or plasma (see col. 4, claim 1, subparagraph (b) and claim 5, subparagraph (a)),

treating the blood or plasma to obtain pooled human immune globulin (see col. 4, claim 1, subparagraph (c)). In light of WO94/13310, WO94/18327 and WO95/34655, the S.aureus strain of Stephan et al comprised Sdr and clumping factor adhesins.

The immunoglobulin composition of Stephan et al would have a titer higher than normal unselected donors. Stephan et al disclose the titer of the human donor immunoglobulin to evidence at least a 2X titer above non-selected donor immunoglobulin (see Table 1, col. 3, line 65-66), wherein the human immunoglobulin was at least 4160 mg/100ml IgG and 480 mg/100ml IgA and 960mg/100 ml/IgM and are relative to the titers shown in Table 1 (see col. 3, lines 1-5)

Inherently the Stephan anticipates the instantly claimed invention, in light of the claims reciting "open" language permitting any number of S.aureus immunogens to be used to be administered to a human host for induction of immunoglobulin.

Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Claim Rejections - 35 U.S.C. § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims (methods) 1-6, 12-17, 23-28, 30-35,37, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (1988, reference of record) in view of Wadstrom (1991, reference of record), and Foster (US Pat. 6,008, 341, reference of record).

The claimed invention is directed to a method of obtaining immunoglobulin compositions from selected donors having an antibody titer to S.aureus clumping factor A, a second staphylococcal adhesin, one of the adhesins is an Sdr adhesin, or collagen binding protein. (Methods:1-6, 12-17, 23-28, 30-35,37, 38-41)

Fischer teach a method of obtaining immunoglobulin the method comprising the steps of:

obtaining selected human donor immunoglobulin compositions produced by selecting plasma donors with high levels of pathogen specific antibody or immunizing donors prior to plasmapheresis (see page 528, last sentence of page bridging to page 529, first paragraph),

identifying, recovering and treating the immunoglobulin to obtain immunoglobulin compositions (IVIG) compositions for treatment of staphylococci infections (see page 529, paragraph 1) based upon in vitro analysis of immunoglobulin compositions that specifically bind to and also has functional activity against staphylococci (see page 529, paragraph 1, lines 5-6).

Fischer teaches the importance of "[physicians should not have to guess about the antimicrobial activity of the IVIG preparations with high levels of pathogen specific antibodies, and teaches that ultimate success of passive immunization "will depend on well-characterized and standardized IVIG products".

The reference differs from the instantly claimed invention by failing to suggest the composition of immunoglobulins comprise S.aureus anti-adhesin antibodies, specifically anti-fibrinogen binding protein (ClfA) and antibodies to an additional adhesion.

Wadstrom, T suggests the formulation of immunoglobulin compositions (anti-adhesin prophylaxis, see page 165, line 11) directed to staphylococcal adhesins fibronectin and collagen binding proteins in an analogous art for the purpose of defining vaccines that are directed to staphylococcal adhesins to combat infection without antibiotic and chemotherapeutic compounds.

Foster et al teaches the formulation of immunoglobulin compositions (see col. 2, lines 51-54; col. 10, lines 63-67) directed to domain A (ClfA, see co. 6, line 15; col. 9, lines 36-37), which comprise antibodies of a titer that is 2x that of the control (see col. 8, lines 30-33) of fibronectin binding protein, a Sdr protein (domain R, see col. 6, line 17) together with other blocking components (see col. 11, lines 11-14), and suggests the administration of the immunoglobulin compositions to humans and animal in an analogous art for the purpose of producing immunoglobulin compositions that can serve to therapeutically treat staphylococcal infection through blocking of adhesin binding to host animal tissues (abstract; col. 10,lines 63-67).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of obtaining immunoglobulin of Fischer to include

obtaining immunoglobulins directed against S.aureus fibrinogen binding protein (ClfA) as taught by Wadstom and Foster, and collagen binding protein as taught by Wadstom , or to administer the antigen to a donor as taught by Fischer, specifically S.aureus fibrinogen binding protein (ClfA) and staphylococcal collagen binding protein as taught by Wadstrom and Foster, to a donor prior to recovering plasma, and

identifying, recovering and treating high titer donor plasma for formulation of high titer immunoglobulin compositions (IVIG) that have anti-ClfA and an additional antibody directed against a second staphylococcus adhesin because Fischer teaches that successful passive immunization of a patient is attainable based upon providing physicians with well characterized human donor immunoglobulin compositions that evidence high levels of binding directed against staphylococci, and Wadstrom and Foster both teach the importance of selecting and characterizing donor immunoglobulin compositions based upon the presence of immunoglobulins to specific adhesins which will serve to prevent establishment of infection and disease by Staphylococcus aureus

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of producing selected human donor immunoglobulin compositions that have high antibody titer for anti-ClfA and a second staphylococcal adhesin, because immunoglobulin compositions for both adhesin molecules were taught, suggested and known in the art as taught by Wadstrom and Foster et al, and selecting an immunoglobulin composition, based upon in vitro analysis for the presence of these antibodies, as taught by Fischer, would provide the medical practitioner with immunoglobulin compositions which would define a greater likelihood of success in treating a immune compromised patient (Fischer).

In view of In re Kerkhoven (205 USPQ 1069, CCPA 1980) which states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the

same purpose in order to form a third composition that is to be used for the very same purpose: idea of combining them flows logically from their having been individually taught in the prior art", Clf-A and a second adhesion of staphylococcus for the realized positive effect of decreased risk of infections caused by S.aureus (see Foster et al, col. 1, lines 22-24).

17. Claims 1-4,38-40, 37, 11,22,29,36 are rejected under 103(a) as being unpatentable over Hook et al (US Pat. 6,288,214, effective filing date May 14, 1997 with priority to May 16, 1996).

The claimed invention is directed to a selected human donor immunoglobulin composition that comprises antibodies to ClfA and a second staphylococcal adhesin, a method of obtaining the composition and a method of using the composition to provide passive immunity.

Hook et al teach the formulation of selected donor immunoglobulin composition that comprises antibodies to ClfA and a second staphylococcal adhesin, wherein the antibodies are directed to ClfA, fibrinogen binding protein and collagen binding protein (see col. 59, section 5,3, Example 3; col. 60, col..61, line 32 and 41-42), shows protective passive immunity through blocking of S.aureus to host receptors with antibodies directed to ClfA and fibrinogen binding protein and collagen binding protein (see section 5.3.10, col. 62) and teaches the production humanized monoclonal antibodies or immunization of human donors with S.aureus adhesin (see col. 12, lines 25-67; col. 18, lines 16-56; col. 19, lines 1-12; col. 31, lines 56-65), purification of

affinity purified antibodies (col. 27, lines 47-61); and the production of human immunoglobulin through immunizing donors (see section 4.10, col. 30, lines 42-65).

Hook et al teaches human immunoglobulin antibodies obtained by immunizing a human donor, wherein the immunogen would induce antibodies to ClfA, collagen binding protein and fibrinogen binding protein, but differs from the instantly claimed invention by failing to show the immunoglobulins obtained from selected human donors.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate selected human donor immunoglobulins to ClfA, and a second staphylococcal adhesin because Hook et al shows the generation of mammalian selected donor immunoglobulin compositions that comprises antibodies specific to ClfA and a second staphylococcal adhesin and teach selected human donor immunoglobulin compositions that comprise these antibodies are preferred (see col. 30, line 52) and are generated by immunizing human donors.

In the absence of a showing of unexpected results the selected human donor immunoglobulin compositions of Hook et al obviate the instantly claimed invention

Conclusion

18. This is a non-final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The

examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp September 13, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Application No. 10/091,494

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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